

## Supplemental Online Content

Danchev V, Min Y, Borghi J, Baiocchi M, Ioannidis JPA. Evaluation of data sharing after implementation of the International Committee of Medical Journal Editors data sharing statement requirement. *JAMA Netw Open*. 2021;4(1):e2033972. doi:10.1001/jamanetworkopen.2020.33972

**eTable.** Description of Clinical Trial Data Repositories

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**eFigure.** Flow Chart of Article Eligibility

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This supplemental material has been provided by the authors to give readers additional information about their work.

## eTable. Description of Clinical Trial Data Repositories

<b>Acronym / short name</b>	<b>Full name</b>	<b>URL</b>	<b>Host organization</b>
CSDR	Clinical Study Data Request	<a href="https://www.clinicalstudydatarequest.com">https://www.clinicalstudydatarequest.com</a>	Consortium of clinical study sponsors/funders
NCTN/NCORP Data Archive	National Clinical Trials Network (NCTN) and NCI Community Oncology Research Program (NCORP) Data Archive	<a href="https://nctn-data-archive.nci.nih.gov">https://nctn-data-archive.nci.nih.gov</a>	National Cancer Institute (NCI)
BioLINCC	Biologic Specimen and Data Repository Information Coordinating Center	<a href="https://biolincc.nhlbi.nih.gov">https://biolincc.nhlbi.nih.gov</a>	National Heart, Lung, and Blood Institute (NHLBI)
YODA	The Yale University Open Data Access (YODA) Project	<a href="https://yoda.yale.edu/">https://yoda.yale.edu/</a>	Yale University
Vivli	Center for Global Clinical Research Data	<a href="https://vivli.org">https://vivli.org</a>	The Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard
DASH	NICHHD Data and Specimen Hub	<a href="https://dash.nichd.nih.gov/">https://dash.nichd.nih.gov/</a>	The Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)
NINDS Archived Clinical Research Datasets	NINDS Archived Clinical Research Datasets	<a href="https://www.ninds.nih.gov/Current-Research/Research-Funded-NINDS/Clinical-Research/Archived-Clinical-Research-Datasets">https://www.ninds.nih.gov/Current-Research/Research-Funded-NINDS/Clinical-Research/Archived-Clinical-Research-Datasets</a>	National Institute of Neurological Disorders and Stroke (NINDS)
BORIS	Bern Open Repository and Information System	<a href="https://boris.unibe.ch/">https://boris.unibe.ch/</a>	University of Bern and the Bern University Hospital
NIDDK Central Repository	NIDDK Central Repository	<a href="https://repository.niddk.nih.gov">https://repository.niddk.nih.gov</a>	National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)
JCHR	JAEB Center for Health Research	<a href="https://www.jaeb.org/">https://www.jaeb.org/</a>	JAEB Center for Health Research

<sup>a</sup> Included are only repositories that were referenced in two or more data sharing statements.

# eAppendix 1. Examples of Data Sharing Statements

<p>Matta MK, Zusterzeel R, Pili NR, et al. Effect of sunscreen application under maximal use conditions on plasma concentration of sunscreen active ingredients. <i>JAMA</i>. doi:10.1001/jama.2019.5586</p> <p><b>Data Sharing Statement</b></p> <p><b>Data</b>  <b>Data available:</b> Yes  <b>Data types:</b> Deidentified participant data  <b>How to access data:</b> Deidentified participant data are provided as an online supplement to the manuscript.  <b>When available:</b> With publication</p> <p><b>Supporting Documents</b>  <b>Document types:</b> .csv file; see Supplement 3</p> <p><b>Additional Information</b>  <b>Who can access the data:</b> Everyone  <b>Types of analyses:</b> For any purpose  <b>Mechanisms of data availability:</b> No restrictions  <b>Any additional restrictions:</b> None</p>	<p><b>Data Sharing Statement</b></p> <p>Fleischer. Effect of Epicutaneous Immunotherapy vs Placebo on Reaction to Peanut Protein Ingestion Among Children With Peanut Allergy. <i>JAMA</i>. Published February 22, 2019. 10.1001/jama.2019.1113</p> <p><b>Data</b>  <b>Data available:</b> No</p>																																																																				
<p>Data Sharing Statement</p> <p>Sparano JA, Gray RJ, Ravdin PM, et al. Clinical and Genomic Risk to Guide the Use of Adjuvant Therapy for Breast Cancer. <i>N Engl J Med</i>. DOI: 10.1056/NEJMoa1904819.</p> <table border="1"> <thead> <tr> <th>Question</th><th>Authors' Response</th></tr> </thead> <tbody> <tr> <td>Will the data collected for your study be made available to others?</td><td>Yes</td></tr> <tr> <td>Would you like to offer context for your decision?</td><td>—</td></tr> <tr> <td>Which data?</td><td>Complete de-identified patient data set</td></tr> <tr> <td>Additional information about data</td><td>De-identified data set via NCI data repository <a href="https://nctn-data-archive.nci.nih.gov">https://nctn-data-archive.nci.nih.gov</a></td></tr> <tr> <td>How or where can the data be obtained?</td><td><a href="https://nctn-data-archive.nci.nih.gov">https://nctn-data-archive.nci.nih.gov</a> Contact: For questions about the NCTN/NCORP Data Archive, please contact NCINCTNDataArchive@mail.nih.gov (link sends e-mail).</td></tr> <tr> <td>When will data availability begin?</td><td>with publication</td></tr> <tr> <td>When will data availability end?</td><td>—</td></tr> <tr> <td>Will any supporting documents be available?</td><td>—</td></tr> <tr> <td>Which supporting documents?</td><td>—</td></tr> <tr> <td>Additional information about supporting documents</td><td>—</td></tr> <tr> <td>How or where can supporting documents be obtained?</td><td>—</td></tr> <tr> <td>When will supporting documents availability begin?</td><td>—</td></tr> <tr> <td>When will supporting documents availability end?</td><td>—</td></tr> <tr> <td>To whom will data be available?</td><td>NCI has created a centralized, controlled-access database, called the NCTN/NCORP Data Archive, for storing and sharing datasets generated from clinical trials of the National Clinical Trials Network (NCTN) to make these datasets available in a timely manner, on appropriate terms and conditions, to researchers who wish to analyze the data in secondary studies to enhance the public health benefit of the original work. 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## Data Sharing Statement

Llanos-Cuentas A, Lacerda MVG, Hien TT, et al. Tafenoquine versus Primaquine to Prevent Relapse of *Plasmodium vivax* Malaria. *N Engl J Med*. DOI: 10.1056/NEJMoa1802537.

Question	Authors' Response
Will the data collected for your study be made available to others?	Yes
Would you like to offer context for your decision?	No
Which data?	Anonymized individual participant data, the annotated case report form, protocol, reporting and analysis plan, data set specifications, raw data set, and analysis-ready data set
Additional information about data	No
How or where can the data be obtained?	Proposals should be submitted to <a href="http://www.clinicalstudydatarequest.com">www.clinicalstudydatarequest.com</a>
When will data availability begin?	Within 6 months of this publication
When will data availability end?	N/A
Will any supporting documents be available?	Yes
Which supporting documents?	Protocol, reporting and analysis plan, data set specifications, and clinical study report
Additional information about supporting documents	No
How or where can supporting documents be obtained?	Proposals should be submitted to <a href="http://www.clinicalstudydatarequest.com">www.clinicalstudydatarequest.com</a>
When will supporting documents availability begin?	Within 6 months of this publication
When will supporting documents availability end?	N/A
To whom will data be available?	For research proposals approved by an independent review committee
For what type of analysis or purpose?	For research proposals approved by an independent review committee
By what mechanism?	Proposals should be submitted to <a href="http://www.clinicalstudydatarequest.com">www.clinicalstudydatarequest.com</a>
Any other restrictions?	A data access agreement will be required
Additional information	No

This statement was posted on January 17, 2019, at NEJM.org.

SPRINT MIND Investigators for the SPRINT Research Group. Effect of intensive vs standard blood pressure control on probable dementia: a randomized clinical trial [published online January 17, 2019]. doi:10.1001/jama.2018.21442

## Data Sharing Statement

### Data

**Data available:** Yes

**Data types:** Deidentified participant data, Data dictionary

**How to access data:** Data will be available in BioLINCC:

<https://biolincc.nhlbi.nih.gov/studies/sprint>

**When available:** beginning date: 07-01-2020

### Supporting Documents

**Document types:** None

### Additional Information

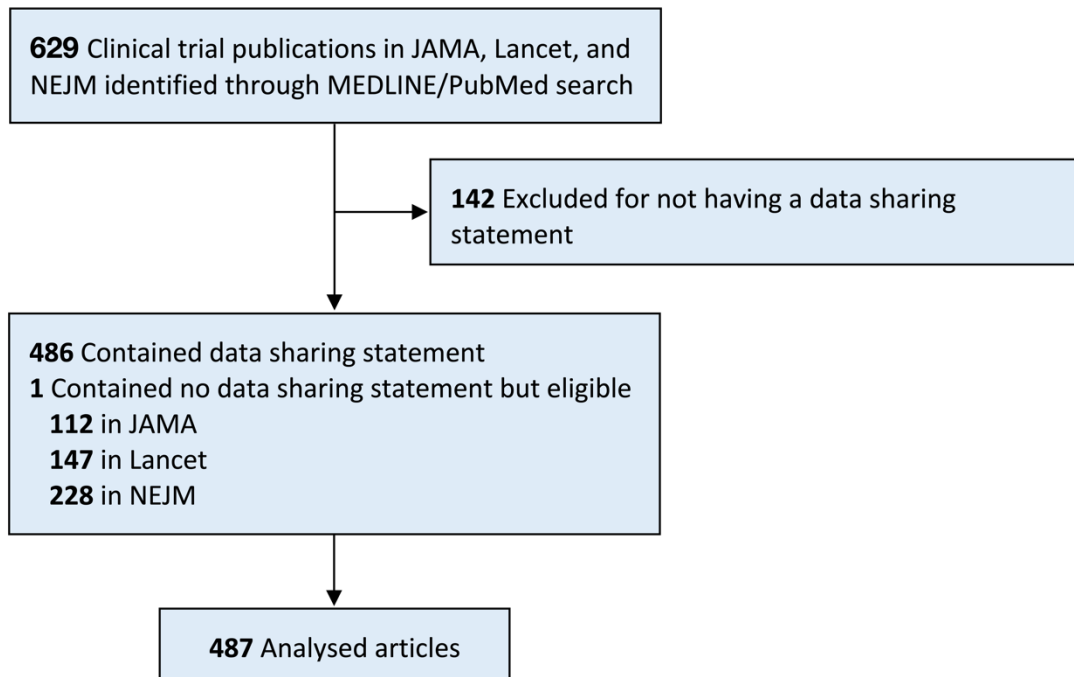
**Who can access the data:** Data will be available for investigators providing an IRB/Ethics approval or certification of exemption from IRB/Ethics review, and also agreeing to the terms and conditions of a data use agreement

**Types of analyses:** Data will be available for any purpose, unless prohibited by the informed consent.

**Mechanisms of data availability:** Data will be available for investigators providing an IRB/Ethics approval or certification of exemption from IRB/Ethics review, and also agreeing to the terms and conditions of a data use agreement.

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**eFigure. Flow Chart of Article Eligibility**



## **eAppendix 2. Codebook**

### **A. Declared data sharing**

1 = YES → Code B, C, D, and F

0 = NO → Code E and F

### **B. Type of declared available data [1 if applicable, blank otherwise]**

Deidentified individual participant data

Aggregate data only

Unspecified/ partial data

### **C. Access to data [1 if applicable, blank otherwise]**

Request to authors

Request to committee/ group/ unit

Request to company

Request to repository/ archive

    Name of repository [Name as noted on DSS]

    Repository contains information about the data/study [1 = Yes, 0 = No]

    Data is available on repository [1 = Yes, 0 = No]

Access unspecified

Data is available to others

### **D. Conditions for data sharing [1 if applicable, blank otherwise]**

Embargo

    Embargo period [in Months]

    If embargo period unspecified, copy wording from the DSS

Collaboration

Product approval

### **E. Reasons for why data not available [1 if applicable, blank otherwise]**

No reason given

Data privacy

Time and cost

Ongoing trial/ research

Regulatory approval

Proprietary data

Shared among co-investigators only

Data may be available for collaboration

Data may be available upon request

### **F. Funder type\***

1 = Industry

2 = Non-industry NIH

3 = Non-industry non-NIH

4 = Mixed (any combination of industry, non-industry NIH, non-industry non-NIH)

\* Only funding is eligible (in-kind support or supplies provided at no charge are not eligible).

## **eAppendix 3. Inclusion Criteria, Search Strategy, and Data Collection and Analysis**

### **Inclusion and exclusion criteria**

In order to be eligible to be selected in the study, a published paper must meet the following inclusion criteria:

1. Publication reports clinical trial results
2. Published in JAMA, NEJM, Lancet
3. Published since July 1, 2018
4. Type of publication is Article
5. Contain a Data Sharing Statement (DSS)\*

\*Articles published in 2020 that meet criteria 1 to 4 are eligible even if no DSS is present as these are likely submitted after July 1, 2018, and therefore fall under the requirements of the ICMJE data sharing policy.

Excluded from the study were publications that contain no Data Sharing Statement due to:

1. Submission prior to July 1, 2018
2. Study not a clinical trial (e.g., observational)
3. Type of publication is letter/correspondence

### **Search strategy**

A MEDLINE/PubMed search was performed on April 4, 2020 using the following search strategy:

((("The New England journal of medicine"[Journal]) OR "JAMA"[Journal]) OR "Lancet (London, England)"[Journal]) AND clinical trial[Publication Type]) AND ("2018/07/01"[Date - Publication] : "2020/04/04"[Date - Publication])

As of April 04, 2020, the search yielded 629 results. Out of those, 486 publications were clinical trials and contained a DSS. One 2020 publication met 1 to 4 inclusion criteria but contained no DSS and was included in the study sample as not sharing data because articles published in 2020 were likely submitted after policy's effective date, July 1, 2018. We conducted a cross-sectional observational study of the resulting sample of 487 articles.

### **Independent review of articles**

For each of the 487 articles, two reviewers independently evaluated the Data Sharing Statement and funding statement, using procedures described in eAppendix 2. Discrepancies were resolved unanimously or by a third reviewer.